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Attorney Docket No. 22918/1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

Lucia Irene Gonzalez-Villasenor

Application No.:

10/080,919

Group Art Unit:

FILED:

February 22, 2002

Examiner:

FOR:

Methods and Composition for Production of Recombinant Peptides

CERTIFICATE OF MAILING BY FIRST CLASS MAIL (37 CFR 1.8)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner of Patents, Washington, D.C. 20231 on:

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Date

INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS)

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

II.	COPIES	
	a. <u>X</u>	Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
III.		EXPLANATION OF THE RELEVANCE ck at least one box)
	a. <u>X</u>	Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
	b	A concise explanation of the relevance of all patents, publications or othe information listed that is not in the English language is as follows:
	C.	The following additional information is provided for the Examiner's

consideration:

FEES

IV.	THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)						
	(check one b	pox)					
	a	within three months of the filing date of a national application (37 C.F.R.					
		§ 1.97(b) (1)). No fee or certification is required.					
	b	within three months of the date of entry of the national stage as set forth in					
		§1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or					
		certification is required.					
	c. <u>X</u>	before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office					
		Action on the merits has been issued, please consider this IDS under 37					
		C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e)below,					
		or, if no certification has been made, charge our deposit account a fee in					
		the amount of \$240.00 as required by 37 C.F.R. § 1.17(p).					
V.	THIS IDS I	S BEING FILED UNDER 37 C.F.R. § 1.97(c):					
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	before the m	nailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. §					
	1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311						
	(See 37 C.F	.R. § 1.97(c) (2)).					
	a	No certification; therefore, a fee in the amount of \$240.00 is required by					
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		or					
	b. <u>X</u>	See the certification below. No fee is required.					

VI. <u>CERTIFICATION UNDER 37 C.F.R. § 1.97(e)</u> (check <u>only</u> one box)

The undersigned hereby certifies that

a	each item of information contained in the IDS was cited in a
	communication from a foreign Patent Office in a counterpart foreign
	application not more than three months prior to the filing of this IDS; or
b	no item of information contained in the IDS was cited in a communication
	from a foreign Patent Office in a counterpart foreign application or, to the
	best of my knowledge after making reasonable inquiry, was known to any
	individual designated in 37 C.F.R. § 1.56(c) more than three months prior
	to the filing of this statement.
c	Some of the items of information were cited in a communication from a
	foreign Patent Office. As to this information, the undersigned certifies
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	of this remaining information contained in the IDS was cited in a
	communication from a foreign Patent Office in a counterpart foreign
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	inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c)
	more than three months prior to the filing of this statement.
	Please charge Deposit Account No. 500369 in the amount of \$180.00 for the
	above-indicated fee. A triplicate copy of this paper is attached.
<u>X</u>	No fee is required.

VII. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.704(d) (PATENT TERM ADJUSTMENT)

Applies to origin	nal applications (other than design) filed on or after May 29, 2000
a	Each item of information contained in the Information Disclosure
	Statement was cited in a communication from a foreign patent office in
	a counterpart application and this communication was not received by
	any individual designated in § 1.56(c) more than thirty days prior to the
	filing of the Information Disclosure Statement.
b. <u>X</u>	Enclosed herewith is form PTO-1449.
c. <u>X</u>	Copies of cited references are enclosed.
d	The listed references were cited in the enclosed International Search.
	Report in a counterpart foreign application.
If the Exam	iner has any questions concerning this IDS, he/she is requested to contact the
undersigned. If it is	s determined that this IDS has been filed under the wrong rule, the PTO is
requested to consid	er this IDS under the proper rule (with a petition, if necessary) and charge the
appropriate fee to I	Deposit Account No. 500369.
	Respectfully submitted,
Date:	
Dutc.	Thomas M. Saunders, Esq.
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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** 10/080,919 INFORMATION DISCLOSURE STATEMENT 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor ART UNIT: FILING DATE: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. DOCUMENT **CLASS** DATE IF DATE INVENTOR CLASS INITIAL NUMBER APPR 06/04/1996 435 69.1 Cousens et. al. 5,523,215 06/30/1987 Rausch et. al. 530 412 4,677, 196 FOREIGN PATENT DOCUMENTS **DOCUMENT NUMBER** DATE COUNTRY CLASS SUB TRAN **CLASS** Y/N 14/495 Y Nov. 27 1990 **EPO** C07K EP 0 433 225 B1 OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Recombinant-DNA-derived bovine growth hormone from Escherichia coli", Keith E. Langley et. al., Eur J. Biochem, 163, pp 313-321, (1987) "Plasminogen activator inhibitor-1 fused with erythropoietin (EPO) mimetic peptide (EMP) enhances the EPO activity of EMP", Le-tian Kuai et.al., J. Peptide Res., 56, 2000, pp 59-62 "Biopharmaceutical formulation", J. Ching Lee, Current Opinion in Biotechnology, 2000, 11, pp 81-84 "Purification and Characterization of Human Interleukin-1 Expressed in Escherichia Coli", Shirley R. Kronheim et.al., Bio Technology, Vol. 4, December 1986, pp 1078-1082 "Expression, renaturation and purification of recombinant human interleukin 4 from Escherichia coli", Anita van Kimmenade et. al., Eur. J. Biochem, pp 109-114 (1988) "Expression of a biologically active fragment of human IgE ε chain in Escherichia coli, Fu-Tong Liu et. al., Proc. Natl. Acad. Sci. USA, Vol. 81, pp 5369-5373, September 1984 "Renaturation of Escherichia coli Tryptophanase after Exposure to 8 M Urea, Evidence for the Existence of Nucleation Centers", Jacqueline London et. al., Eur. J. Biochem. 47, 409-415 (1974) "Inclusion Bodies from Proteins Produced at High Levels in Escherichia coli", Joanna K. Krueger et. al., Amer. Assoc. for the Adv. Science, 1990, pp 136-142 "Refolding of Recombinant Proteins", Tadahiko Kohno et. al., Methods in Enzymology, Vol 185, pp 187-195, 1990 "E. coli expression and characterization of a mutant troponin I with the three cysteine residues substituted", Lan Kluwe et. al., FEBS, Vol 323, number 1.2, pp 83-88, May 1993 Date: Examiner:

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		OTHER DOCUMENTS (INCLUDING AU	THOR, TITLE,	DATE, PERTINE	NT PAGES, E	rc.)	
"Production of a biologically active novel go Comparative Biochemistry and Physiology, F						coli, Soheil S. l	Mahmoud e	t. al.,
	ji A	"Intermediates in the Folding	ng Reactions of Sn	nall Proteins", Pet	er S. Kim et. al., <u>An</u>	nu. Rev. Bioch	em, 1990, 5	9, 631-660
	12	"Refolding and Association 250	of Oligomeric Pro	oteins", Rainer Ja	enicke et. al., <u>Metho</u>	ds in Enzymolo	<u>ogy,</u> 1986, 1	31, pp 218-
	13	"Preparation of Biologicall coli", J. Hoppe et. al., Bioc			ype BB from a Fusio	on Protein Expr	essed in Esc	cherichia
	14	"Pathways of Protein Foldi	ng". C. Robert Ma	tthews, Annu. Re	v. Biochem. 1993, 6	2, 653-683		
	15	"The Purification of eukary 240, 1-12	otic polypeptides	synthesized in <i>Esc</i>	cherichia coli", Fion	a A. O. Marston	n, <u>Biochem</u>	<u>J</u> . (1986),
	16	"Purification of biologically Vol. 80, pp 906-910, Febru		us 40 small tumor	antigen", Ilan Bikel	et. al., <u>Proc. N</u>	atl. Acad. S	ci. USA,
	١٦	"Recombinant Chicken and Oncorhynchus Kisutch", Ja					le Pacific Sa	almon
	"Renaturation of Enzymes after Polyacrylamide Gel Electrophoresis in the Presence of Sodium Dodecyl Sulfate", Sanford A. Lacks et. al., The Journal of Biological Chemistry, Vol. 255, No. 15, August 10 1980, pp 7467-7473							te", 73
	19	"Cloning and expression of Acad. Sci. USA, Vol. 82, July 10, 100 and 1			in Escherichia coli'	', Susumu Sekii	ne et. al., <u>Pr</u>	oc. Natl.
	Lυ	"Purification of Calf Proch Bio/Technology, Septembe			Escherichia Coli, Fic	ona A.O. Marsto	on et. al.,	
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	34	"Purification of recombinan Letters, Vol. 13, No. 6, 389		ormone expresse	d in <u>Escherichia co</u>	oli, Seiji Sugimoto	o, <u>Biotechn</u>	ology
	ろう	"Protein engineering to opti Transactions, Vol 16, pp 11		protein purificati	on", Mathias Uhle	n et. al., <u>Biochen</u>	nical Society	¥
	34	"Solubilization and activation of the Meeting, Cardiff, Vol.		calf prochymosir	n from <i>Escherichia</i>	coli", FIONA A	O. MARS	TON, et al.,
	94)	"Sequencing of a cDNA end Biochimica et Biophysica A	coding the human ccta 1217 (1994) 3	fast-twitch skelet 38-340	al muscle isoform	of troponin I", Le	ei Zhu et. al	
	"Reconstitution of Lactic Dehydrogenase. Noncovalent Aggregation vs. Reactivation. 1. Physical Properties and Kinetics of Aggregation". Gerd Zettlmeissl et. al., <u>Physical Properties of LDH Aggregates</u> , Vol 18, No. 25, 1979, 5567-5571							and 79, 5567-
	"Increase of Solubility of Foreign Proteins in <i>Escherichia coli</i> by Coproduction of the Bacterial Thioredoxin". Takashi Yasukawa; <u>The Journal of Biological Chemistry</u> , Vol. 270, No. 43, October 27, 1995, pp 25328-25331							Takashi
	3.5	"Efficient and Rapid Affinity Purification of Proteins Using Recombinant Fusion Proteases", Philip A. Walker et. al., Bio/Technology, Vol. 12, June 1994, pp 601-605						
	"Effects of Low Concentrations of Guanidine. HC1 on the Reconstitution of Lactic Dehydrogenase from Pig Muscle in vitro – Evidence for Guanidine Binding to the Native Enzyme", Gerd Zettlmeissl et. al., <u>Eur. J.Biochem</u> , 100, pp 593-598 (1979)							
	41.	"High-level direct expression met-free product", Hisahi Y						erminus
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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** INFORMATION DISCLOSURE STATEMENT 10/080,919 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor FILING DATE: ART UNIT: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. DOCUMENT EXAM. **CLASS** DATE IF CLASS INITIAL NUMBER DATE INVENTOR APPR FOREIGN PATENT DOCUMENTS TRAN **CLASS** SUB DOCUMENT NUMBER DATE COUNTRY CLASS Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Troponin I is present in human cartilage and inhibits angiogenesis", Marsha A. Moses et. al., <u>Proc. Natl. Acad. Sci.</u> USA, Vol. 96, pp 2645-2650, March 1999 "Structure, evolution, and regulation of a fast skeletal muscle troponin I gene", Albert S. Baldwin et. al., Proc. Natl. 22 Acad. Sci. USA, Vol. 82, pp 8080-8084, December 1985 "Utilization of Zeolite Y in the removal of anionic, cationic and nonionic detergents during purification of proteins", Zoltan Blum et. al., Biotechnology Techniques, Vol 5, No. 1, pp 49-54, (1991) "Principles that govern the folding of Protein Chains", Christian B. Anfinsen, SCIENCE, 20 July 1973, Volume 181, Number 4096, pp 223-230 "Overexpression of human cardiac troponin-I and troponin-C in Escherichia coli and their purification and characterization - Two point mutations allow high-level expression of troponin-I", Eman AL-HILLAWI et. al., Eur. J. 45 Biochem., 225, pp 1195-1201, (1994) "Recombinant protein expression in Escherichia coli", François Baneyx, Current Opinion in Biotechnology, 1999, Vol. 46 10, pp 411-421 "Structure and morphology of protein inclusion bodies in Escherichia coli", Gregory A. Bowden, Bio/Technology, Vol 9, 11.7 August 1991, pp 725-730 "Renaturation, purification and characterization of recombinant Fab-fragments produced in Escherichia coil", Johannes 45 Buchner et. al., Bio/Technology, Vol. 9, February 1991, pp 157-162 49 "Stabilization of Protein Structure by Sugars", Tsutomu Arakawa et. al., Biochemistry, 1982, Vol. 21, pp 6536-6544 "Synthesis and cloning of a gene coding for a fusion protein containing mouse epidermal growth factor", G. Allen et.al., Journal of Biotechnology, Vol. 5, (1987) pp 93-114 51 "Denatured States of Proteins", Ken A. Dill, Annu. Rev. Biochem., 1991, Vol. 60, pp 795-825 Date: Examiner:

Sheet 6 of 10

INFO)RM	FORM PTO-1449 ATION DISCLOSURE STA	ATEMENT		OCKET NO.		SERIAL NO. 10/080,919		
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	54	"Choice of Cellular Protein 5.16.1-5.16.34	Expression System	m", David Gray e	t. al., Current Protoc	ols in Protein S	cience, (200	00), pp	
	53	"Chromatofocusing", Alan	"Chromatofocusing", Alan Williams, Current Protocols in Protein Science, (1997), pp 8.5.1-8.5.10						
	ri4	"Overview of Protein Purification and Characterization", R.K. Scopes, <u>Current Protocols in Protein Science</u> , (1995), pp 1.1.1-1.1.5							
	ちら	"Strategies for Protein Puri	fication", R.K. Sco	opes, Current Prot	ocols in Protein Scient	ence, (1995), pp	1.2.1-1.3.7	1	
	SE-	"Conventional Chromatographic Separations", Ben. M. Dunn, <u>Current Protocols in Protein Science</u> , (1997), pp 8.0.1-8.1.9							
	5.7	"Dominant Forces in Protei	in Folding", Ken A	. Dill, <u>Biochemis</u>	try, Vol. 29, Numbe	r 31, August 7,	1990, pp 71	133-7155	
	58	"Nativelike Secondary Structure in Interleukin-1ß Inclusion Bodies by Attenuated Total Reflectance FTIR", Keith Oberg et. al., Biochemistry, 1994, Vol. 33, pp 2628-2634							
	54	"Efficient rentaturation and fibrinolytic properties of prourokinase and a deletion mutant expressed in <i>Escherichia coli</i> as inclusion bodies", Gaetano Orsini et. al., <u>Eur. J. Biochem</u> , Vol. 195, pp 691-697 (1991)							
	(- ("Culture of Yeast for the Pr Science, (1995), pp 5.8.1-5		ologous Proteins"	, Michael A. Roman	os et. al., <u>Curre</u>	nt Protocol	s in Protein	
	El	"Solubility as a function of protein structure and solvent components", Catherine H. Schein, Bio/Technology, Vol. 8, April 1990, pp 308-317							
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	ζż	"Synthesis of calf prochyme 3671-3675, June 1983	osin (prorennin) ii	in Escherichia coli", J.S. Emtage, Proc. Natl. Acad. Sci. USA, Vol. 80, pp					
	i-3	"High-Level Expression in <u>DNA</u> , Volume 4, Number 4			tive Bovine Grow	th Hormone", He	nry J. Georg	ge et. al.,	
	64	"Purification of Recombina	nt Proteins", Paul	T. Wingfield, Cur	rent Protocols in	Protein Science, 1	997, 6.0.1	6.7.10	
	65	"Reconstitution of Lactic D Denatured Aggregates", Ra						versibly	
	66	"Gene Expression in Recon	nbinant <i>Escherich</i>	ia coli", Joan Stad	ler, 1995, pp 1-51	***************************************	•		
	ĖT	"Gene Expression in Recon 55-120	nbinant Bacillus",	Matti Sarvas, <u>Ger</u>	ne Expression in R	ecombinant Moc	roorganisms	<u>s</u> , 1995, pp	
	68	"Use of Stabilizing Additiv	es", Ciaran O'Fag	gain, <u>Stabilizing Pr</u>	otein Function, 19	997, pp 69-79			
	ЬG	"Recombinant human insul Bio/Technology, Vol. 5, Oc			Escherichia coli'	', Thomas C. Furi	man et. al.,		
	7.	"High-Level Expression and Purification of the Recombinant Diphtheria Fusion Toxin DTGM for PHASE I Clinical Trials", Arthur E. Frankel et. al., Protein Expression and Purification, 16, 190-201, (1999)							
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Y DOCKET NO. SERIAL NO. **FORM PTO-1449** INFORMATION DISCLOSURE STATEMENT 10/080,919 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor ART UNIT: FILING DATE: February 22, 2002 UNITED STATES PATENT DOCUMENTS SUB FIL. EXAM. DOCUMENT **CLASS** DATE IF INITIAL. NUMBER DATE INVENTOR CLASS APPR FOREIGN PATENT DOCUMENTS SUB TRAN DOCUMENT NUMBER **CLASS** DATE COUNTRY CLASS Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Recovery of soluble, biologically active recombinant proteins from total bacterial lysates using ion exchange resin". Adolf Hoess et. al., Bio/Technology, Vol. 6, October 1998, pp 1214-1217 "Renaturation of Recombinant Proteins Produced as Inclusion Bodies", Bernhard E. Fischer, Biotech. Adv., Vol. 12, pp 71 89-101, 1994 "Refolding and crystallographic studies of eukaryotic proteins produced in Escherichia coli", Kiyoshi Nagai et. al., 73 Biochemical Society Transactions, 1988, Vol. 16, pp 108-110 "Protein folding intermediates and inclusion body formation", Anna Mitraki et. al., Bio/Technology, Vol. 7, July 1989, 14 pp 690-697 "Overview of Protein Expression in Saccharomyces cerevisiae", Robert L. Strausberg, Production of Recombinant 75 Proteins, 1995, pp 5.6.1-5.6.7 "Production of recombinant proteins", Paul T. Wingfield, Current Protocols in Protein Science, Supplement 20, 2000, pp 76 5.0.1-5.16.25 "Fermentation and Growth of Escherichia coli for Optimal Protein Production", Alain Bernard et. al., Current Protocols in Protein Science, 1995, pp 5.3.1-5.3.18 "Protein Folding and its Implications for the Production of Recombinant Proteins", Roman Hlodan et. al., Biotechnology 73 and Genetic Engineering Reviews, Vol. 9, December 1991, pp 47-88 "Reconstitution of Rabbit Skeletal Muscle Troponin from the Recombinant Subunits All Exressed in and Purified from E. coli, Setsuko Fujita-Becker et. al., J. Biochem., 114, 438-444, (1993) "A novel sequential procedure to enhance the renaturation of recombinant protein from Escherichia coli inclusion bodies", Bernhard Fischer et. al., Protein Engineering, Vol. 5, No. 6, pp 593-596, 1992 Examiner: Date:

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT

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et. al., Biotechnology Techr	niques, Vol. 10, No Purification of I	ntra Cellular Accumulated Proteins fr	***			
"Convenient and Efficient I.	n Vitro Folding of	Disulfide-Containing Globular Proto , Vol. 127, pp 435-444 (2000)	ein from Crude	Bacterial Inc	clusion	
"Enzyme Applications", M.	D. Trevan et. al.,	Biotechnology: The Biological Princ	<u>iples,</u> 1987, pp 2	203-210		
		f Recombinant Porcine Growth Horn el Cardamone et. al., <u>Biochemistry</u> 19			d State and	
"The use of EDTA or Polyn C.R. Dean et. al., <u>Biotechno</u>	nyxin with Lyson; logy Techniques,	zyme for the Recovery of Intracellula Volume 6, No. 2 March/April 1992 p	r Products from	Escherichi	a coli",	
"Serodiagnosis of Antibodic Cabradilla, <u>Bio/Technology</u>		AIDS Retrovirus with a Bacterially Sy 1986, pp 128-133	nthesized ENV	Polypeptide	", Cirilo D	
"Aggregation and Denatural 1993, 32, 3877-3886	tion of Apomyogl	obin in Aqueous Urea Solutions", Li	nda R. De Youn	g et. al., <u>Bio</u>	ochemistry,	
"Refolding of recombinant p	proteins", Eliana I	De Bernadez Clark, <u>Biochemical Eng</u>	ineering, 1998,	9, 157-163		
"Pharmacoeconomics", Jose	eph F. Heyse et. al	l., Encyclopedia of Biopharmceutical	Statistics, 2000	, pp 387-40	1	
"Recombinant DNA Proteir Drugs, 1988, pp 3-6	ns and Drug Disco	very", Christopher Hentschel, <u>Genet</u>	ically Engineere	d Human T	herapeutic	
"Chapter 8. Bioproducts and	d Economics", Ha	rvey W. Blanch et. al., <u>Biochemical I</u>	Engineering, 19	96, pp 609-6	571	

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ATTY DOCKET NO. SERIAL NO. **FORM PTO-1449** 10/080,919 INFORMATION DISCLOSURE STATEMENT 22918/1 APPLICANT(S): Lucia Irene Gonzalez-Villasenor ART UNIT: FILING DATE: February 22, 2002 UNITED STATES PATENT DOCUMENTS **SUB** FIL. EXAM. DOCUMENT CLASS DATE IF DATE **INVENTOR** CLASS INITIAL NUMBER APPR FOREIGN PATENT DOCUMENTS SUB **CLASS** TRAN DATE **COUNTRY DOCUMENT NUMBER CLASS** Y/N OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.) "Solubilization of Protein Aggregates", Fiona A. O. Marston et. al., Methods in Enzymology, Vol. 182, pp 264-276, 1990 94 "Development of an Intravenous y-Globulin with Fc Activities", Y Masuho et. al, Vox Sang. 32: p 175-181 (1977) "Reversible protection of disulfide bonds followed by oxidative folding render recombinant hCGB highly immunogenic". 95 Asok Mukhopadhyay, Vaccine, 18 (2000) 1802-1810 "Refolding of Therapeutic Proteins Produced in Escherichia coli as Inclusion Bodies", Satoru Misawa et. al., 96 Biopolymers, 51, 297-307, (1999) "Global Suppression of Protein Folding Defects and Inclusion Body Formation", Anna Mitraki et. al., Science, Vol. 253, 97 pp 54-58 "Structural characterization of the human fast skeletal muscle troponin I gene (TNN12)", Antony J. Mullen et. al., GENE, 95 242, (2000) 313-320 Date: Examiner: